CIOMS FORM

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	3a. WEIGHT	4-6 REACTION ONSET		
		Day	Month	Year				Day	Month	Year
PRIVACY	EL SALVADOR		PRIVACY		50 Years	Female	225.00 kg	22	JUL	2025

7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data)

Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas)	Product	Serious	Listed	Reporter Causality	Company Causality
Death (unknown cause) [Death]	LYNPARZA	Yes	No	Not Related	Not Related

(Continued on Additional Information Page)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☒ PATIENT DIED
  Date: 22-JUL-2025
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ANOMALY
- ☐ OTHER

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)
#1) LYNPARZA (OLAPARIB) Film-coated tablet {Lot # Unknown}

15. DAILY DOSE(S)
#1) 150 milligram, q12h

16. ROUTE(S) OF ADMINISTRATION
#1) Oral use

17. INDICATION(S) FOR USE
#1) (Not Coded)

18. THERAPY DATES(from/to)
#1) 04-MAY-2023 / 21-JUL-2025

19. THERAPY DURATION
#1) 2 years 2 months 18 days

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ YES ☐ NO ☒ NA

21. DID REACTION REAPPEAR AFTER REINTRODUCTION?
☐ YES ☐ NO ☒ NA

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.)
From/To Dates — Type of History / Notes — Description
Unknown

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
AstraZeneca
Serban Ghiorghiu
1 Medimmune Way
Gaithersburg, Maryland 20878 UNITED STATES
Phone: +1 301-398-0000

26. REMARKS
World Wide #: SV-ASTRAZENECA-202507CAM018199SV
Patient ID: PER-3671685
Study ID: Unknown
Center ID: Unknown(continued)

24b. MFR CONTROL NO.
202507CAM018199SV

25b. NAME AND ADDRESS OF REPORTER
NAME AND ADDRESS WITHHELD.

24c. DATE RECEIVED BY MANUFACTURER
22-JUL-2025

24d. REPORT SOURCE
☒ STUDY ☐ LITERATURE
☒ HEALTH PROFESSIONAL ☐ OTHER:

DATE OF THIS REPORT
25-JUL-2025

25a. REPORT TYPE
☒ INITIAL ☐ FOLLOWUP:

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case Description: A report has been received from a other health professional, regarding a patient enrolled in an early access program concerning a female adult patient born in 1975 (age 50 years, height 165 cm, weight 225 kg).

No medical history was reported and no concomitant products were reported.

On 04-MAY-2023, the patient started treatment with Lynparza (olaparib) (batch number(s) Unknown) 150 milligram q12h, Oral use.

Treatment with Lynparza (olaparib) was Not Applicable.

The patient died (preferred term: Death) on 22-JUL-2025 with Fatal outcome.

The patient died on 22-JUL-2025. It was not known whether an autopsy was performed. The cause of death was death.

The reporter considered the event as serious due to death criterion.

The reporter did not consider that there was a reasonable possibility of a causal relationship between Lynparza and the following event: death (unknown cause).

The company physician did not consider that there was a reasonable possibility of a causal relationship between Lynparza and the following event: death (unknown cause).

26. Remarks continued

Case References: SV-AstraZeneca-CH-00915945A